

XIII. 510(K) SUMMARY JUL 25 2003

Modified Nurse's Assistant® O.R. Control System

In accordance with 21 CFR section 807.92, ConMed Integrated Systems is submitting the following 510(k) summary:

1) Date Submitted

June 25, 2003

2) Submitter Information

ConMed Integrated Systems

1815 NW 169th Place, Suite 4020

Beaverton, OR 97006

Contact: C. Jeff Lipps, BS/MBA, Dir. of RA

Phone (503) 614-1106 ext. 1206

Fax (503) 614-1109

3) Name of Device

Proprietary Name: Nurse's Assistant® O.R. Control System

Common Name: Surgical Control Center

Classification Names: Surgical Lamp, 878.4580
Endoscope and accessories, 876.1500
Gynecologic laparoscope and accessories,
884.1720

Laparoscopic insufflator, 884.1730

Electrosurgical cutting and coagulation device
and accessories, 878.4400

Medical image hardcopy device, 892.2040

Product Codes: FSY, GCJ, FET, KOG, HET, HIF, GEI, LMC

Classification Panel: General & Plastic Surgery

Device Class: Class II

1 of 3

510(k) Summary – Modified Nurse's Assistant® O.R. Control System

Page 2

4) Predicate Devices

This device is substantially equivalent to the ConMed Integrated Systems' Nurse's Assistant® O.R. Control System (K010754), Modification to Olympus' Integrated Endosurgery System EndoALPHA (K022270), and Modification to Computer Motion's HERMES Operating Room Control Center (K030240).

5) Device Description

The Nurse's Assistant® is a programmable controller operated through a touch screen GUI that offers professional O.R. staff a simplified remote user interface and a real time display of settings for the devices attached to the system thereby eliminating the necessity for using the various control panels on diverse surgical equipment.

6) Intended Use

The Nurse's Assistant® is intended to be used to turn on and off, and adjust certain settings of, endoscopic and surgical cameras, electrosurgical generators such as the ConMed System 5000 ESU, laparoscopic insufflators such as the Linvatec GS1002 Insufflator, surgical lamps, operating room ("O.R.") lights, and operate digital documentation products, VCR's, video monitors, video printers, radics and CD players.

7) Indications for Use:

The Nurse's Assistant® is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thorascoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy. A few examples of the more common surgical procedures where this system could be used are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anteriorspinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated, examination of the evacuated cardiac chamber during performance of valve replacement, arthroscopic meniscus repair, anterior cruciate ligament repair and associated procedures.

510(k) Summary – Modified Nurse's Assistant® O.R. Control System

Page 3

8) Applied Safety Standards:

The Nurse's Assistant® O.R. Control System has been tested to the following standards:

Test	Title
IEC 601-1	International Standard for Medical Electrical Equipment
IEC 601-1 Amendment 1	International Standard for Medical Electrical Equipment
IEC 601-2-18	International Standard for Medical Electrical Equipment
EN 60601-1	International Standard for Medical Electrical Equipment
EN 60601-1-1	General Requirements for Safety – Collateral Standard
EN 60601-1-2 (2001)	International Standard for Medical Electrical Equipment, Electro Magnetic Compatibility (EMC)
CAN/CSA C22.2 601.1-M90	Medical Electrical Equipment - Part 1: General Requirements for Safety, General Instruction No. 1; Supplement 1; 1994 R(1997)
UL 2601-1, 2 nd Ed.	UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety, 2 nd Ed.
EN 55011	Conducted Emissions
EN 55011	Radiated Emissions
IEC 61000-4-2	Electrostatic Discharge
IEC 61000-4-3	Radio Frequency Electromagnetic Fields
IEC 61000-4-4	Fast Transients Common Mode
IEC 61000-4-5	High Energy Surge
IEC 61000-4-6	Conducted Immunity



JUL 25 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. C. Jeff Lipps
Director of Regulatory Affairs
ConMed Integrated Systems
1815 NW 169th Place, Suite 4020
Beaverton, Oregon 97006

Re: K031979

Trade/Device Name: ConMed Integrated Systems' Nurse's Assistant[®] O.R. Control System

Regulation Number: 21 CFR 876.1500, 878.4580, 884.1720

Regulation Name: Endoscope and accessories, Surgical lamp,
Gynecologic laparoscope and accessories

Regulatory Class: II

Product Code: GCJ, KOG, FET, FSY, HET

Dated: June 25, 2003

Received: June 26, 2003

Dear Mr. Lipps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

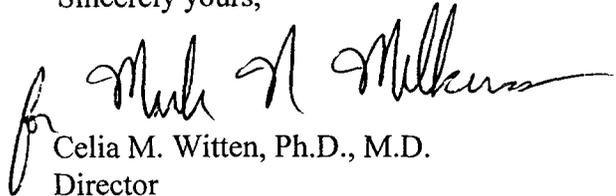
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. C. Jeff Lipps

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a long horizontal stroke at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XIV. INDICATIONS FOR USE STATEMENT

510(k) Number: **K031979**

Device Name: **Modification to ConMed Integrated Systems' Nurse's Assistant® O.R. Control System**

Indications for Use:

The Nurse's Assistant® is a programmable controller operated through a touch screen GUI that offers professional O.R. staff a simplified remote user interface and a real time display of settings for the devices attached to the system thereby eliminating the necessity for using the various control panels on diverse surgical equipment.

The Nurse's Assistant® is intended to be used to turn on and off, and adjust certain settings of, endoscopic and surgical cameras, electrosurgical generators such as the ConMed System 5000 ESU, laparoscopic insufflators such as the Linvatec GS1002 Insufflator, surgical lamps, operating room ("O.R.") lights, and operate digital documentation products, VCR's, video monitors, video printers, radios and CD players.

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[Handwritten Signature]
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031979

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use

(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)